

**CODE OF PRACTICE FOR THE
MARKETING OF MEDICINES
IN SOUTH AFRICA**

Code of Practice for the Marketing of Medicines in South Africa

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Introduction

The ethical promotion of medicines is vital in helping to ensure that health care professionals and the public have access to the information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

All marketers of medicines should maintain high ethical standards when conducting promotional activities and must comply with applicable legal, regulatory and professional requirements. Compliance with the Code will ensure that ethical promotional practices are established for all marketers, prescribers, dispensers, advisers and users of medicines. The overarching philosophy is a principle of compliance with the spirit of the Code.

The "Code of Practice for the Marketing of Medicines in South Africa" is referred to throughout as "the Code".

The National Department of Health, the pharmaceutical industry and other stakeholders are committed to the provision of affordable and quality health care for all South Africans. High quality, effective and accessible medicines are a cornerstone of healthcare. Accurate information about medicines is integral to providing quality health care services.

This Code is issued in terms of section 18C of the Medicines and Related Substances No 101 of 1965, and is adopted by pharmaceutical trade associations to signify the industry's commitment to ensure that marketing of medicines to health care professionals and the public is carried out in a responsible, ethical and professional manner, based on practical and scientifically validated information.

The pharmaceutical industry is committed to educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the rational use of medicine and fair competition in the marketing of medicine. The industry seeks to preserve the independence of the decisions taken by healthcare professionals. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of medicines. Industry relationships with healthcare professionals must support, and be consistent with the professional responsibilities healthcare professionals have towards their patients.

This Code takes cognisance of other professional and industry codes applicable to the pharmaceutical sector and professions it interacts with.

1. Application clause:

1.1. What the Code covers

The Code is applicable to:

- i. all registered medicines licence holder, their agents, contractors, 3rd party distributors / marketers. Companies that circumvent the code by engaging or using other companies or agents will be infringing the code.
- ii. all advertising and promotional activities and communication directed at influencing any member of the medical, dental, pharmacy, nursing or allied health professions who in the course of his or her professional activities may prescribe, purchase, supply, administer a medicine or recommend the use of a medicine.
- iii. It also covers advertising material, which is directed to members of the public to inform the general public about the medicines available for self medication.

- iv. All advertising and promotion and all activities directly or indirectly related to marketing which may reflect on the marketing practices of the pharmaceutical industry, including but not limited to sponsorships, patient information-sharing, meetings and entertainment.
- v. Interactions between the pharmaceutical industry and healthcare professionals (Part IA) and the pharmaceutical industry and the general public (Part IB)
- vi. Material issued by companies that relates to medicines but which is not intended as promotional material for those medicines per se, for example corporate advertising, press releases, market research material, financial information to inform shareholders, the stock exchange, should be examined to ensure that it does not contravene the Code or the relevant statutory requirements.

1.2 What the Code does not cover

- i. Factual, accurate, informative announcements and reference material concerning registered medicines and relating, for example, to adverse reactions and warnings.
- ii. The following documents are not covered by the Code:
 - a. Trade catalogues to suppliers including price lists.
 - b. Product labels, packaging materials and in-pack leaflets. These are subject to the labelling and package insert requirements in terms of the Regulations to the Medicines and Related Substances Act and the Guidelines pertaining thereto.
- iii. The marketing or promotion of veterinary medicines, complementary medicines and medical devices.
- iv. Issues relating to pricing, bonus and perverse incentives governed elsewhere in legislation and in codes issued in terms of the Medicines Act, National Health Act, etc.
- v. The conduct of clinical or non-interventional studies. However, Clause 6.4 requires that clinical and non-interventional studies must not be "disguised promotion".
- vi. **Not** applicable to wholesalers, distributors and logistics companies **except** to the extent that they may influence the demand for medicines.

2. Interpretation of the Code

- 2.1. The provisions in this Code should be interpreted in light of both the letter and spirit of the Code. Guidance notes, issued from time to time by the Marketing Code Authority will provide companies with an indication as to how the Code should be applied and adhered to, in practical terms. The rulings of the bodies established as part of the Marketing Code Authority, forms precedent on what constitutes acceptable practices in the marketing of medicines.
- 2.2. The Code should not be construed in conflict with any existing law applicable to the marketing of Medicine, including but not limited to the Medicines and Related Substances Act No 101 of 1965, the Patents Act No 57 of 1978, the Copyright Act No 98 of 1978, the Trade Marks Act No 194 of 1993 and the National Health Act No 61 of 2003.
- 2.3. Any interpretation of the provisions of this Code as well as interaction with health care professionals not specifically addressed in this Code should be made in light of the following principle:
 "Companies shall adhere to ethical business practices and socially responsible industry conduct and shall not use any unlawful or any unethical inducement in order to sell, recommend or arrange for the sale or prescription of their products."
- 2.4. In any review of advertising material or promotional activities covered by this Code, consideration will be given not only to the impression created by a careful study of an advertisement or activity, but also to the impression likely to be gained from a brief or partial exposure.

3. Status of the Guidelines to the Code

Guidance on the interpretation of the Code appears as supplementary information to the text in a separate document, Guidance Notes on the South African Marketing Code. The examples given are intended to illustrate and clarify the meaning of the Code. They are not exhaustive and do not cover all possible situations to be covered by the provisions of the Code.

These Guidelines will be updated regularly by the Code Authority, as part of its mandate to ensure education, application and enforcement of the Code. These guidelines will also be used to regularly update applicable monetary values and examples of conduct that constitutes violations of the Code. The Code Authority has the power to refer issues not within the scope and ambit of this Code, to the appropriate authorities, councils or bodies with the authority to deal with such issues.

DRAFT VERSION

Scope

Part IA: The marketing and promotion of medicines to health care professionals

Part IA of the Code applies to the promotion of all medicines to members of the healthcare professions, and to appropriate administrative staff by the pharmaceutical industry or by other health professions such as those involved in managed health care or medical schemes, regardless of the scheduling status of the medicine.

It includes the marketing and promotion of self-medication products to health care professionals when such promotion is aimed at generating prescriptions or recommendations to patients.

Advertising of medicines in Schedules S0 and S1 to the general public is permitted but advertising of medicines in Schedules S2 to S6 to the general public is not allowed under the Medicines Act and Regulations.

Part 1 B The marketing and promotion of medicines directly to the consumer

The advertising of medicines in Schedules S0 and S1, to the general public is permitted by law. The main purpose of the Code is to help ensure that advertising of self-medication medicines complies with applicable codes and laws. The Code is applied in spirit as well as in principle.

The scope of Part 1B relates to all self-medication (S0 and S1) medicines registered or sold in terms of the Medicines and Related Substances Act (Act 101 of 1965 as amended). Part 1B of the Code applies to advertising materials and promotional activities for medicines, as defined by the Medicines and Related Substances Act, which are aimed at general public and persons who may legitimately purchase medicines on behalf of other consumers (e.g. parents, who purchase medicines on behalf of their children). The provisions of Part I B of the code do not apply to advertising aimed at health care professionals.

Part II: Enforcement of the Code

The Code is based on the principle of self regulation of the industry through a procedure for handling complaints which is in line with international standards and practice, but made binding through the legislative recognition of the self-regulatory and subsequent processes which may include the Medicines Regulatory Authority.

The process of enforcement and the relevant bodies responsible for such enforcement are set out in Part II of this Code.

The Code Authority has the power to refer issues not within the scope and ambit of this Code to the appropriate authorities, councils or bodies with the authority to deal with such issues.

Glossary

Note: In this Code, words and phrases that are defined in the Medicines and Related Substances Act No. 101 of 1965 as amended shall bear the same meanings as they do in the Act and all regulations issued in terms of this Act.

The following additional definitions are provided to guide the interpretation of this Code.

Advertising and promotional materials or activities, include, but are not limited to Advertorials; Branded materials relating to product sponsorship; Aerial promotions such as on hot air balloons and / or blimps; Booklets; Cinema commercials; Consumer leaflets; Consumer broadsheets; Direct mail materials; Website and other Internet materials, including press releases intended for internet publication; On-pack statements; Outdoor advertising; Point of sale materials; Posters; Print advertisements (for use in newspapers, magazines, etc.); Promotional aids including those used for direct selling activities; Promotional scripts for use by telephone helplines; Promotional text messages; Consumer promoters; Telephone help lines; Television and radio/audio commercials; Sports, art and other sponsorships; Airport, washroom, shopping centre advertising; Touch screen advertising; Aisle, ceiling, floor advertising and other signs; Counter top advertising; Window displays; Gondola end advertising; Bunting; Advertising on electronic ordering systems; Bus, taxi and other vehicle advertising; and Light box advertising.

Company: may refer to a company, closed corporation, organisation, vendor or individual who may sell or promote medicines.

Company Code Compliance Officer: means anyone duly authorised by the company, or appointed by the company in writing, to sign documents or give instructions on behalf of the company

Electronic journals: Electronic versions of journals that can be viewed online via any personal computer or other electronic device.

Health care professional (HCP): includes members of the medical, dental, pharmacy or nursing professions and any other persons registered with a professional council or body who in the course of their professional activities may prescribe, recommend, purchase, evaluate, supply or administer a medicine as registered under Act 101.

Honorarium: is a payment or an award granted in recognition of a special service by a professional person. Honorariums can be paid fair market value for speeches, articles, appearances or other services rendered.

Medicines Act (i.e. Medicines and Related Substances Act 101 as amended): refers to the body of legislation governing the registration and marketing of medicine, as amended from time to time.

Promotional item: is merchandise given away free of charge in an effort to create awareness of a company or product.

PART 1A: THE MARKETING AND PROMOTION OF MEDICINES TO HEALTH CARE PROFESSIONALS

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Part 1A: The marketing and promotion of medicines to health care professionals

1 Registration

A medicine must not be promoted prior to the product being registered by the Medicines Control Council [MCC] or if a medicine for which an application has been submitted in terms of Section 14(3) of the Act ("old medicine"), which permits its sale, supply and use in South Africa.

The promotion of a medicine must be in accordance with the terms of its registration, and must not be inconsistent with the particulars listed in its package insert.

2 Advertising and Promotional Material

2.1 The approved package insert may be used as a reference in all promotional material and advertising.

2.1.1 The minimum requirements must:

- a. conform with the applicable regulations in terms the Medicines Act.
- b. form part of the promotional material and not be separate.
- c. be included in all promotional material (except for promotional items – see Clause 14.3).
- d. be provided in a clear and legible manner
- e. be consistent with the most recently approved package insert for the medicine.

2.1.2 In **all** forms of advertising i.e. written, audio, audio-visual, internet, the statement "For full prescribing information refer to the package insert approved by the Medicines Control Council" should appear or be stated. This does not apply promotional items as referred to in clause 14.3

2.1.4 In the case of an advertisement included as part of independently produced information on the Internet, the statement should be in the form of a direct link between the first page of the advertisement and the minimum information.

2.1.5 In the case of printed promotional material consisting of more than two pages, the minimum information can appear either the first or last page.

2.1.7 Promotional material other than advertisements appearing in professional publications must include the date or a code number identifying the version on which the promotional material was drawn up or last revised.

2.2. Audio-visual or audio material such as films, video recordings, sound bytes, interactive data systems and such like:

- a) the minimum information may be provided either by way of a document that is made available to all persons to whom the material is shown or sent, or by inclusion on the audio-visual recording or in the interactive data system itself.
- b) When the minimum information is included in an interactive data system, instructions for accessing it must be clearly displayed.
- c) If the material that consists of sound only, the minimum information may be provided by way of a document that is made available to all persons to whom the material is played or sent.

2.3 **Journal Advertising**

An advertisement which contains two or more pages must not be false or misleading when each page is read in isolation.

An advertisement taking the form of a loose insert in a journal may not be of a size larger than the page size of the journal itself.

Advertisements in journals must not resemble editorial matter unless clearly identified as advertorial or as a sponsored feature.

In the case of a journal advertisement where the prescribing information appears overleaf, a reference to where it can be found must appear in a type size which is legible at either the beginning or the end of the advertisement.

3 **Information, Claims and Comparisons**

3.1 **Accuracy, balance, fairness of claims**

Information, claims and comparisons whether in advertisements, promotional items, product detailing and all information relating to medicines, whether verbal or in writing, must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence, and must reflect that evidence clearly. Such information or the manner in which it is portrayed, must not mislead either directly or by implication by distortion exaggeration or undue emphasis.

Material must be sufficiently complete to enable the recipients to form their own opinion of the therapeutic value of the medicine.

Any information, claim or comparison must be capable of substantiation. No substantiation is required for claims in the package insert which has been approved by the Medicines Control Council.

3.2 **Exaggerated or misleading claims**

Promotion material must encourage the rational use of medicine by presenting it objectively and without exaggerating its properties. Exaggerated or all-embracing claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.

3.3 **Comparisons**

A comparison in the marketing and promotion of medicines is only permitted in promotional material if:

- a) it is not misleading or disparaging;
- b) medicines or services for the same needs or intended for the same purpose are compared;
- c) one or more material, relevant, substantiable and representative features are compared;
- d) no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, proprietary names, other distinguishing marks and those of a competitor;
- e) the trademarks, proprietary names, other distinguishing marks, medicines, services, activities or circumstances of a competitor are not discredited or denigrated.
- f) Trade marks/ Trade names or company names of another company may only be mentioned with written permission from the another company;
- g) no unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing marks of a another company;
- h) medicines or services are not presented as imitations or replicas of goods or services bearing another company trade-mark or trade name.

3.4 **Substantiation**

Substantiation for any information, claim or comparison must be provided without delay at the request of members of the health professions or appropriate administrative staff. It need not be provided in relation to the validity of a MCC approved indication (s) in the package insert.

3.5 **References**

When promotional material refers to published studies, clear and complete references must be given.

3.6 **Unpublished supporting data**

When promotional material refers to (unpublished) data on file, the relevant part of this data must be provided without delay at the request of members of the health professions or appropriate administrative staff.

If confidential information, such as information relating to trade secrets, sensitive commercial information or information of a competitive nature is involved, the material may be given to an independent arbitrator acceptable to both parties or a person appointed by the Code Authority from its Adjudication Panel for assessment, in the case of a dispute. The arbitrator or person appointed by the Code Authority will make an assessment as to whether the unpublished data in fact support the statement(s) made in the promotional material.

3.7 **Artwork**

All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.

3.8 **Use of the word 'safe'**

The word 'safe' or words containing reference to safety must not be stated in such a way as to imply that a product has no side effects, toxic hazards or risks of addiction. The word 'safe' must not be used without scientific substantiation.

3.9 **Use of the word 'new'**

The word 'new' must not be used to describe any product or presentation, which has been generally available, or any therapeutic indication, which has been available for more than twelve months in South Africa.

3.10 **Other claims**

It must not be stated that a product has no side-effects, toxic hazards or risk of addiction or dependency.

4 **Disparaging References**

4.1 The medicines, products and activities of other pharmaceutical companies must not be disparaged.

4.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

5 High standards, Format, Suitability and Endorsement by HCP's

- 5.1 All material and activities must recognise the special nature of medicines, and the professional standing of the audience to which they are directed and must not be likely to cause offence. High standards must be maintained at all times.
- 5.2 The name or photograph or film of a member of a health profession must not be used in any way that is contrary to the applicable professional Codes for that profession and all endorsements, where permitted by professional Codes, have to be done within the scope of such Codes.
- 5.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.
- 5.4 Promotional material must not include any reference to the Medicines Control Council unless this is specifically required by the MCC, through the applicable legislative and other provisions. This provision does not preclude references to important MCC Guidelines and Policies, such as those on the reporting of adverse events, which serves as important regulatory frameworks for the utilisation of a medicine.
- 5.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.
- 5.6 The telephone, SMS, e-mail, telex or facsimile machines must not be used for promotional purposes, except where, when first contact is made, the option is provided to opt out and the decision is subsequently respected. The option to opt out should also be provided on all subsequent communications, even if the addressee has not opted out after the first contact.
- 5.7 All material relating to medicines and their uses, which is sponsored by a pharmaceutical company, must clearly indicate the details of the company that sponsored it.
The only exception to clause 5.7 is market research material that need not reveal the name of the company involved but must state that a pharmaceutical company sponsors it.
- 5.8 Postcards, other exposed mailings, envelopes or wrappers must not carry matter which may be regarded as advertising to the general public contrary to Clause 15.

6 Disguised Promotion

- 6.1 Promotional material and activities must not be disguised.
- 6.2 Market research activities, post-marketing surveillance studies, post authorisation studies, clinical trials and the like must not be disguised promotion, nor contain or lead to disparaging comments about competitors or their products. Such trials / studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.
- 6.3 Clinical trials should not be undertaken solely for the purpose of promotion.
- 6.4 Observational / Non-interventional Studies of registered medicines are studies where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the approved MCC package insert.

The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study.

No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

- The study is conducted with a scientific purpose and there must be:
 - i) a written study plan (protocol) and
 - ii) written contracts between healthcare professionals and/or the institutes at which the study will take place, on the one hand, and the company sponsoring the study, on the other hand, which specify the nature of the services to be provided and, subject to clause(s) immediately below, the basis for payment of those services;
 - a) Remuneration provided must be reasonable and of fair market value to the work performed;
 - b) Study protocol should be submitted to the ethics committee for review;
 - c) Personal data privacy (including the collection and use of personal data) must be respected;
 - d) The study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
 - e) The study protocol must be approved by the company's scientific / medical department, who must also supervise the conduct of the study
 - f) The study results must be analysed by or on behalf of the contracting company and summaries thereof must be made available within a reasonable period of time to the company's scientific service, which service shall maintain records of such reports for a reasonable period of time. The company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to Code Authority upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the MCC. In addition, companies are encouraged to publicly disclose the summary details and results of non-interventional studies in a manner that is consistent with the parallel obligations with respect to clinical trials.
 - g) Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

7 Provision of Reprints and the Use of Quotations

- 7.1 Reprints of articles in journals must not be provided unsolicited unless the articles have been published in a peer reviewed publication in line with good principles of scientific review and publication. When providing a reprint of an article about a medicine, it should be accompanied by prescribing information. If a non-peer-reviewed article is requested by a health care professional, a copy may be provided on written request.
- 7.2 Quotations from medical and scientific literature must accurately reflect the meaning of the author(s). If unpublished, "personal communications" shall not be used unless the company, organisation or individual is able to supply written substantiation upon request.

- 7.3 Quotations taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as medical conferences or symposia relating to medicines, must not be used without the formal permission of the speaker unless there is a published record of the proceedings and this is accurately given as a reference.
- 7.4 Utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

8 Distribution of Promotional Material

- 8.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.
- 8.2 A company that is requested by an addressee to seize or limit the volume of promotional material should respect the wishes of the addressee.
- 8.3 Mailing lists must be kept up-to-date. Requests from health care professionals to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at their request or with their permission.

9 Scientific Information Service

- 9.1 Every company must compile and collate information about the medicines they market, and must be able to provide such information to authorities, members of health care professions or the general public, where appropriate. This may include information about adverse drug events.

10 Certification of Promotional Material, Meetings and Other Activities

- 10.1 **Appointment of person (s) responsible as company Code Compliance Officer for approval of promotional material, meetings or activities**
Promotional material and activities must not be approved nor issued unless its final form, to which no subsequent amendments will be made, has been certified by an individual on behalf of the company i.e. the company Code Compliance Officer.

The appointed company code compliance officer should either be the responsible pharmacist or a natural person responsible for the enforcement and compliance with the Act.

Each company or individual should have a Standard Operating Procedure [SOP] for the approval process. The SOP must be available for auditing by the Code Authority or the MCC according to MCC auditing requirements.

Activities which would be subject to certification include, but are not limited to, CPD or similar professionally-required educational events, the presentation of scientific or promotional material, journal club meetings organised and/or sponsored by the company, etc.

Meetings that fall within the ordinary scope of the day-to-day activities of company representatives, and/or where the events, parts of the event, a speaker or an attendee is not sponsored by the company, are not covered by the provisions of clause 10.1.

10.2 **The certificate**

The certificate must state that the company Code Compliance Officer has examined the final form of the material or arrangements for an event and that it is in accordance with the requirements of the relevant advertising regulations and this Code, is not inconsistent with the product registration and the package insert and is a fair and truthful presentation of the facts about the medicine.

10.3 **Recertification of promotional material.**

Material that is still in use must be re-certified at intervals of no more than two years to ensure that it continues to conform to the relevant regulations and the Code.

10.4 **Retention of documentation.**

Companies, organisations or individuals shall preserve all certificates and the relevant accompanying information for not less than five years after the final use of the promotional material or the date of the meeting and produce them on request from Code Authority or the MCC.

In relation to certificates for promotional material, the material must be preserved in the form certified with information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination. It is, however, in the interest of storage space, acceptable to store accurate photographic or other electronic representations of material, information or items.

All documents /material relating to marketing and promotion, irrespective of the nature of the campaign or event have to be retained for the minimum period.

11 **Medical Sales Representatives**

11.1 **Training of medical sales representatives**

Each Company shall ensure that its sales representatives, including personnel retained by way of contract with third parties, and any other company representatives who call on health care professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicinal products (each, a "medical representative") are familiar with the relevant requirements and all applicable laws and regulations related to the promotion and advertising, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote or services offered.

11.2 **Compliance with Codes and laws by medical sales representatives**

Medical sales representatives must comply with all relevant requirements of the applicable professional and good practices codes and all applicable laws and regulations, and companies are responsible for ensuring their compliance.

- 11.3 **Gaining interviews**
Medical sales representatives must not employ any inducement or subterfuge to gain an interview. No fee should be paid or offered for the granting of an interview. Donations to charities in return for medical representatives gaining interviews are prohibited. Donations in lieu of hospitality are unacceptable. In an interview, or when seeking an appointment for one, medical sales representatives must at the outset take reasonable steps to ensure that they do not mislead as to their identity or the company that they represent.
- 11.4 **Organising meetings**
Medical sales representatives organising meetings are permitted to provide appropriate hospitality and/or to meet any reasonable, actual costs, which may have been incurred. All meetings have to conform with the provisions of Clause 13.
- 11.5 **Consideration for health care professionals and others**
Medical representatives must ensure that the frequency, timing and duration of calls on health care professionals, pharmacies, hospitals, other healthcare facilities, medical schemes or funders and the like, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom medical representatives wish to call, and the arrangements in force at any particular establishment, must be observed.
- 11.6 **Information to scientific service of company**
Medical representatives must transmit to the scientific service of their companies (Clause 9) any information that they receive in relation to the use of the medicines that they promote, particularly reports of adverse drug events.
- 11.7 **Information to be provided to health care professionals**
When medical representatives introduce a medicine to a health care professional for the first time, they should provide a copy of the latest approved package insert or another relevant document containing the same information. On subsequent occasions, such information should be available on request.
- 11.8 **Follow up on requests for information**
If discussion on a medicine is initiated by the person or persons on whom a medical representative calls, the medical representative is not obliged to have available the information on that medicine referred to in Clause 11.7, but shall ensure the speedy delivery of the requested material.
- 11.9 **Detailed briefing materials**
Companies may prepare detailed briefing material for medical representatives on the technical aspects of each medicine that they will promote. Briefing material must comply with the relevant requirements of the Code and must be approved by the company Code Compliance Officer in the company or organisation.
- 11.10 **Company responsibility for medical representatives**
Companies are responsible for ensuring that the activities of their medical sales representatives comply with the Code and all applicable laws and regulations.


12 Training

- 12.1 All personnel, including members of staff concerned in any way with the preparation or approval of promotional material or of information to be provided to members of South African health professions and to appropriate administrative staff or of information to be provided to the public, must be fully conversant with the requirements of the Code.

13 Interactions with healthcare professionals

13.1 Hospitality/ Venues of meetings and events

Companies, organisations or individuals are permitted to organise or sponsor meetings and events including Continued Professional Development (CPD). The following should be adhered to:

- a. The merit and focus of the meeting should be clearly scientific and/or educational.
- b. The venue and hospitality should be secondary to the meeting both in time allocation and focus.
- c. The venue should be appropriate and conducive to the scientific or educational objectives and the purpose of the event or meeting.
- d. Hospitality, meals and entertainment should be modest. As a general rule, hospitality must not exceed what the health care professionals would normally be prepared to pay for themselves.
- e. Invitations should not be extended to spouses or other guests except if they are health care professionals or administrative staff i.e. any costs incurred by spouses or other guests cannot be reimbursed or paid for by the company.
- f. Inappropriate financial benefit or material benefits including excessive hospitality cannot be offered.
- g. For product launches, no sponsorship or payment of travel and accommodation can be extended to health care professional.
- h. For **speakers**, payment of reasonable honoraria and reimbursement of out of pocket expenses, including travel is permissible provided it is in terms of a written contract.
- i. CPD meetings:
 - No product promotion is allowed in the CPD meeting room. Company-branded items / promotion is permissible.
 - Speakers should use the INN names of products during CPD events.
 - Product promotional material displayed outside of the CPD meeting room should not be accessible to the general public, if it is not permissible to market such product directly to the public.
- j. For local CPD events and product launches which are held in major metropolitan areas, reasonable travel arrangements or travel reimbursement can be made to ensure that the health care professional who do not reside / practice in a major metropolitan  [a1] are able to access the applicable information.
- k. The criteria for selection of attendees / invitees must be transparent and available to the Code Authority for scrutiny.

13.1.2 For medical or scientific congress, conferences or seminars held in South Africa, internationally or international meetings organised overseas and held in South Africa

- a. Meetings organised by pharmaceutical companies, other organisations or individuals at venues outside South Africa, that are educational and scientific nature and involve South African health care professionals are acceptable.
- b. The rationale for any meeting, or sponsorship to attend a meeting, is to be transparent, valid and cogent.

- c. Consideration must be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, hospitality provided and the like.
- d. As with any meeting, it should be the programme that attracts delegates and not the associated hospitality or venue and all entertainment and events have to be subordinate in time and nature to the sponsored meeting, congress, conference or seminar.
- e. Payment of registration fees, travel and accommodation must be made to professional associations / organisers and not directly to health care professional or appropriate administrative staff, unless proof is received that the amounts spend are in the name of the sponsored person and do not exceed to items which forms part of the agreed sponsorship. No payment may be made to the professional / staff for time spent at the event.
- f. Sponsored speakers may receive reasonable honoraria

13.1.3 **Sponsorship of meetings of patient support groups**

Patient support group meetings and events may be sponsored provided that proper records are kept and that no product promotional takes place.

13.1.4 **Transparency**

When meetings are sponsored by pharmaceutical companies, other organisations or by individuals, the fact must be disclosed in the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

13.1.5 **Stand-alone entertainment, leisure, social or cultural events with health care professionals**

Meetings organised for patients, general public, individual or groups of doctors, other health care professionals and/or for administrative staff that are wholly or mainly of an entertainment, leisure, social or sporting nature is not permitted.

No stand alone entertainment or other leisure, social or sporting activities may be planned, arranged or funded by pharmaceutical companies as these are unrelated to the promotion of scientific or educational objectives.

13.2 **Other interactions with health care professionals**

13.2.1 **Consultancy services**

The engagement of a health care professional to provide genuine consultancy or other genuine services to a company is permitted.

Healthcare professionals that provide consulting services to a company and are still practising their profession must declare their employment arrangement with the company whenever they write or speak in public about a matter that is the subject of the employment or any other issue relating to that company. Such arrangement must be formalised in a written agreement.

13.2.2 **No direct payments to health care professionals for any other services**

Payments may not be made to doctors or groups of health care professionals, either directly or indirectly, for rental for rooms or other services.

13.3 Certification of Meetings

For the purposes of certification envisaged in clause 10, the following details have to be retained:

- a. Details of the programme, both scientific/education and entertainment/hospitality, if any,
- b. Invitations, the choice of venue(s)
- c. documentation as to the rationale for the meeting or sponsorship,
- d. participant selection processes and criteria,
- e. the anticipated and actual costs associated with the event, as well as that associated with all entertainment and hospitality.

14 Inducements, gifts and promotional items; competitions

14.1 Inducements

There should be no personal enrichment of health care professionals or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials, or the general public as an inducement to prescribe, supply, stock, dispense, administer or buy any medicine, subject to the provisions of Clause 14.2. No donation should unjustifiably enrich health professionals performing a health related service.

14.2 Gifts and promotional items

Occasional gifts and promotional items to healthcare professionals and appropriate administrative staff are acceptable provided that they are:

- Inexpensive and of minimal intrinsic value i.e. within the cost limit set from time to time by the Code Authority
- Not for personal use e.g. No entertainment CD's / DVD's, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment.
- educational and / or scientific value, benefit the patient and/or be relevant to the practise.

14.3 Promotional items

It is permissible to brand promotional items. The minimum information for a medicine as required under Clause 2 does not have to be included on a promotional aid provided that no promotional claims are made. The following information may be included on such items:

- The name of the medicine
- An indication that the name of the medicine is a trade mark
- Relevant company name / logo, or product name / logos

14.4 Cultural courtesy gifts

An inexpensive gift not related to the practice of medicine, the value of which will determined by the Code Authority, may be given on an infrequent basis to health care professional in recognition of significant national, cultural or religious days.

14.5 Competitions

Competitions should fulfill the following criteria:

- the competition is based on medical/ product knowledge or the acquisition of scientific knowledge;
- the prize is directly relevant to the practice of medicine or pharmacy; and
- individual prizes or educational item offered and within the cost limit set from time to time by the Code Authority.
- Entry into a competition must not be dependent upon prescribing, ordering or recommending of a product and no such condition shall be made or implied.

14.6 Donations and grants to charities

Financial donations, or other appropriate donations to registered charities or other institutions may be made if properly recorded and approved by the responsible person (s) in each company or organisation. Donations, grants and benefits in kind to institutions, organisations or associations are only allowed provided:

- they are made for the purpose of supporting healthcare or research;
- they are documented and kept on record by the donor/grantor; and
- they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

Donations must not be paid directly to healthcare professionals.

Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them covered in this Section.

14.6 Corporate Social Investment

Donations to meet identified corporate social responsibility projects may also be made if judged on its merits, approved by the responsible person(s) in each company or organisation and documented.

15 Relations with the General Public and the Media

15.1 Medicines must not be advertised to the general public if they are prescription only medicines or are medicines, which, though not prescription only, may not legally be advertised to the general public. This prohibition does not apply to vaccination campaigns or other public health campaigns carried out by companies and approved by the Department of Health and/or MCC.

15.2 Information that is made available to the general public either directly or indirectly about medicines must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading or disparaging with respect to the safety of the product. Statements, representations or tie-off lines must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine.

Clause 15.1 does not prohibit education or information relating to substitution of a medicine or information on safe use, storage of a medicine in general.

15.3 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer should be recommended consultation with his or her own health care professional.

- 15.4 Companies are responsible for information that is issued by their public relations agencies about their products.
- 15.5 Patient education ("help-seeking advertisements") directed at general public is acceptable, provided that it:
- Does not contain the name of the specific medicine
 - Does not make or allude to a medicinal claim
 - Does not provide any risk information
 - Let's the public know that treatment exists for a medical condition
 - "For more information, refer to your doctor or pharmacist (or health care professional)" is mentioned.

16 Samples

- 16.1 The supply of samples is not permitted to extend beyond the conditions as prescribed under the Medicines Act.

17 The Internet

- 17.1 Access to promotional material directed at a South African public provided on the Internet in relation to Schedule 2 to Schedule 6 should be limited through a password protection scheme to health care professional and appropriate administrative staff only.
- 17.2 Information or promotional material covered by Clause 17.1 about medicines which is placed on the Internet outside South Africa will be regarded as within the scope of the Code if it was placed there by a South African company, organisation or individual or an affiliate of a South African company, organisation or individual or at the instigation or with the authority of such a company, organisation or individual, and it makes specific reference to the availability or use of the medicine in South Africa.
- 17.3 Medicines covered by Clause 17.1 may be advertised in a relevant, independently produced electronic journal intended for health care professionals or appropriate administrative staff which can be accessed by non-healthcare professionals.
- 17.4 Package inserts for medicines covered by Clause 17.1 above may be included on the Internet and be accessible by members of the public provided that they are not presented in such a way as to be promotional in nature.
- 17.5 It should be made clear when a user is leaving any of the company sites, or sites sponsored by the company, or is being directed to a site, which is not that of the company.

18 Compliance with Undertakings

- 18.1 When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure that it complies with that undertaking.

Part 1B: The marketing and promotion of medicines directly to the general public

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DRAFT VERSION

Part 1 B. THE MARKETING AND PROMOTION OF MEDICINES TO THE GENERAL PUBLIC

1. Registration

A medicine shall not be promoted prior to the product being registered by the Medicines Control Council or is a medicine for which an application has been submitted in terms of Section 14(3) of the Act ("old medicine"), which permits its sale, supply and use in South Africa.

The promotion of a registered self-medication product must be in accordance with the terms of its registration and must not be inconsistent with the particulars listed in the package insert or approved text.

2. Advertising

- 2.1 Advertisements must be consistent with the requirements of the Medicines Act.
- 2.2 Advertisements shall not mislead or disparage either directly or by implication. Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and supportable and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The use of medical terminology is acceptable provided that this does not confuse or mislead the consumer.
- 2.3 Advertising shall not be misleading as to the nature of the product, its ingredients or indication (s).
- 2.4 Advertisements must not contain any other express or implied exaggerated claims as to the benefits that can be obtained from use of the medicine.
- 2.5 Efficacy claims should clearly state if medicines are intended to be used over extended periods of time or where the medicine is indicated for disease risk reduction or prevention.
- 2.6 Advertising can refer to the prevention of symptoms and use of a product in chronic conditions, if in line with the registered indication. The advertisement shall make it clear under what circumstances use of the product is appropriate. This is particularly important in therapeutic areas where individuals may be asymptomatic.
- 2.7 Advertising shall not cause consumers unwarranted anxiety with regard to any condition. Nor should it suggest that suffering might arise if a consumer fails to respond to the advertisement's claim. Advertising must not suggest that the condition will deteriorate or that it will become more severe if the individual does not use the medicine featured. Language which brings fear or distress should not be used.
- 2.8 Advertisements should not suggest that using a medicine could enhance normal good health or be a substitute for a healthy diet and lifestyle.
- 2.9 Advertising shall not be aimed principally or exclusively at children (under the age of 18 years).
- 2.10 Advertising shall not show children using, or within reach of, medicine without adult supervision.

- 2.11 Advertising shall encourage responsible self-medication and should not encourage individuals to exclusively self-diagnose. Nor should it encourage self diagnosis where medical intervention is required. Particular care should be taken where symptoms are generalised and a diagnosis is made by exclusions of more serious complaints or where use of the medicine could mask the symptoms of a more serious condition.
Advertisements should encourage individuals to share information with the pharmacist or healthcare practitioner so that they can ensure the medicine will be suitable for the intended user.
- 2.12 Advertising shall not suggest that a medical consultation or surgical operation is unnecessary nor shall it discourage consumers from seeking medical or pharmaceutical advice. Consideration should be given to the inclusion of information concerning the availability of professional advice.
- 2.13 Advertising shall not offer to diagnose, advise, prescribe or treat personally by correspondence.
- 2.14 Advertising shall not claim guarantees on a product's effects, safety or quality.
- 2.15 Advertising shall not encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any medicine.
- 2.16 Advertisements should not be flippant or use inappropriate imagery or imagery out of context. Advertisers are encouraged to convey the message that medicines should be treated with respect and may not be suitable for some people.
- 2.17 Sponsored advertorials shall be appropriately identified as such in the particular publication at the place where it appears, in order to be distinguished from editorials.
- 2.18 Advertising should not encourage consumers to discontinue the use of prescribed medicines.
- 2.19 Advertising shall not contain recommendation of a product by scientists or health professionals unless substantiated.
- 2.20 Advertising shall not include a recommendation by a person who, because of their celebrity status, may encourage consumers to take a particular medicine.

3. Information, Claims and Comparisons in advertising

- 3.1 All advertising must be consistent with the provisions of the Medicines Act of 1965 as amended i.e. all advertising must give the information necessary for the correct use of a product as approved by the Medicines Control Council and may not deviate from, be in conflict with or go beyond the evidence submitted in the application for registration with regard to its safety, quality and efficacy in respect of what has been approved by the Council and incorporated in the approved package insert.
- 3.2 In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the package insert of the medicine.
- 3.3 A written advertisement for a medicine shall comply with regulation 45 of the Medicines Act of 1965 as amended.

- 3.4 Advertising shall not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type.
- 3.5 Advertising should not suggest that a product's effects are better than or equal to another identifiable product or treatment.
- 3.6 Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products other than as permitted by the Medicines Control Council.
- 3.7 Trade names of products of other companies shall not be used without permission of the owner.
- 3.8 Hanging (open ended) comparisons are not allowed.
- 3.9 Comparisons are only permitted in advertising or promotional material if:
- they are not misleading or disparaging;
 - medicines or services for the same needs or intended for the same purpose are compared;
 - one or more materials, relevant, substantiable and representative features are compared;
 - no confusion is created between the medicine advertised and that of a competitor or between the advertiser's trade marks, proprietary names, other distinguishing marks and those of a competitor;
 - the trademarks, proprietary names, other distinguishing marks, medicine, services, activities or circumstances of a competitor are not discredited or denigrated. Trade marks/proprietary name of a competitor may only be mentioned with a written permission from the competitor;
 - no unfair advantage is taken of the reputation of a trade mark, proprietary name or other distinguishing marks of a competitor;
 - medicines or services are not presented as imitations or replicas of goods or services bearing a competitor's trademark or trade name.
- 3.10 Substantiation for any information, claim or comparison must be provided at the request of the Authority. It need not be provided, however, in relation to the validity of indications approved in the product registration.
- 3.11 When a written advertisement refers to published studies, clear and complete references must be listed on the advertisement.
- 3.12 When a written advertisement refers to unpublished data on file, the relevant part of this data must be provided at the request of the Code Authority.
- 3.13 All artwork including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code.
- 3.14 Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matters with which they deal, and must not be included unless they are relevant to the claims or comparisons being made.
- 3.15 Information and claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. It must not be stated that a product has no side effects, toxic hazards or risks of addiction. It is acceptable to highlight the absence of a specific side effect, e.g. 'no drowsiness'. The word 'safe' or phrases containing reference to safety must not be used without adequate scientific substantiation.

- 3.16 Exaggerated, all embracing claims or superiority claims must not be made and superlatives must not be used except for those limited circumstances where they relate to a clear fact about a medicine. Claims should not imply that a medicine or an active ingredient has some special merit, quality or property unless this can be substantiated.
- 3.17 The word 'new' must not be used to describe any product or presentation, which has been generally available or any therapeutic indication, which has been available on the market for more than twelve months in South Africa.
- 3.18 Advertising of a self-medication medicine shall not suggest that a product is a foodstuff, cosmetic or other non-medicinal product.
- 3.19 Although it is acceptable to indicate that a self-medication medicine is palatable, advertising shall make clear that it is a medicine.
- 3.20 Advertising shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.
- 3.21 A product, or any of its attributes, shall not claim to be unique unless substantiated.
- 3.22 Advertising shall not mislead about the novelty of a preparation.
- 3.23 Advertising claims relating to speed of absorption, dissolution, distribution or other pharmacokinetic particulars are acceptable if supported by evidence and if in line with the product's registration dossier. However, such evidence may not be extrapolated to claims that a product offers improved efficacy or speed of efficacy, without supporting evidence to substantiate such claims.
- 3.24 Advertising shall not suggest that the safety or efficacy of a product is due to the fact that it is natural unless this has been clinically proven as per current clinical guidelines. Advertising shall not claim that a product is 'natural' unless all of its components are naturally occurring. 'Natural' can only be used to describe those elements that are naturally occurring e.g. 'natural ingredient'.
- 3.25 Advertising shall not suggest that a product is herbal, unless all the active ingredients are plants or extracts of plants. 'Herbal' can only be used to describe those elements that are of plant origin e.g. 'herbal ingredient'.
- 3.26 Claims for weight management, meaning weight loss, measurement reduction, clothing size reduction and weight control/maintenance, can only be made in conjunction with reference to sensible lifestyle factors including a diet and exercise

4. Disparaging References

- 4.1 The medicine, products and activities of other companies must not be disparaged.
- 4.2 The health professions and the clinical and scientific opinions of their members must not be disparaged.

5. Suitability and Taste

- 5.1 All material and activities must recognise the special considerations relating to the promotion of the medicine and must not be likely to cause offence.
- 5.2 The name or photograph or film of a member of a health profession must not be used in any way that is contrary to the conventions of that profession.
- 5.3 Promotional material must not imitate the devices, copy, slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse.
- 5.4 Promotional material must not include any reference to the Medicines Control Council unless this is specifically required by the Council.
- 5.5 Reproductions of official documents must not be used for promotional purposes unless permission has been given in writing by the appropriate body.
- 5.6 All material relating to medicines and their uses, which is sponsored by a company must clearly indicate that that company, organisation or individual has sponsored it. Market research material need not reveal the name of the company, organisation or individual involved but must state that a company, organisation or individual sponsors it.

6. Prohibitions or Restricted Representations

- 6.1 An advertisement for a self-medication medicine must not refer, expressly or by implication to products curing or assisting in the treatment of serious forms of diseases, conditions, ailments or defects unless prior approval is given under the Medicines Act, as amended.

7. Quotations

Quotations relating to medicine taken from public broadcasts, for example radio, television or Internet, and from private occasions, such as medical conferences or symposia, must not be used without the written permission of the speaker.

8. Testimonials

- 8.1 Testimonials shall comply with the approved package insert and with the other principles of this Code.
- 8.2 Testimonials should be less than 3 years old and be the genuine views of the user.
- 8.3 The use of healthcare professionals for marketing, promotion, endorsements or testimonial has to take place within the scope set by the professional codes applicable to such professionals.

9. Health professionals

- 9.1 Advertising shall not claim that a product is, or has been available on prescription. However, it is acceptable to state that a product's active ingredient, formulation or preparation has been prescribed by a health professional, provided there is evidence that this is the case.
- 9.2 Advertising shall not refer to a 'college', 'hospital', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists.

10. Views of authors

The utmost care must be taken to avoid ascribing claims or views to authors when these no longer represent the current views of the authors concerned.

11. Scientific Information Service

All companies, organisations or individuals must compile and collate all information about the medicine that they market, and must be able to provide such information to authorities, members of health care professions or the general public, where appropriate. This may include information about adverse drug reactions.

12. Certification of Promotional Material

The same process and principals stipulated in clause 10 of Part 1A of the code applies in the context of Part 1B.

13. Relations with the General Public and the Media

- 13.1 Requests from individual members of the public for information or advice on personal medical matters must be refused and the enquirer advised to consult his or her own health professional.
- 13.2 Companies are responsible for information about their products that is issued by their public relations agencies.

14. Promotions, gifts, prizes and inducements

- 14.1 No company shall be involved in promotional schemes which are hazardous to the public or which bring the industry into disrepute.
- 14.2 Entry into consumer competitions shall not be dependent on the conditional purchase of a medicine nor shall a medicine be offered as a prize. The value of the prize shall not exceed the limits set by the Code Authority from time to time.

15. Hospitality meetings

Companies may provide hospitality to persons or appropriate administrative staff in association with professional, scientific and promotional meetings/events, provided that it is reasonable and subordinate to the main purpose of the meeting or event.

16. Training and Education

Companies may provide training or education for general public and may also sponsor training provided by other organisations. Such materials should offer accurate, balanced information on the subject area and include a clear indication of which company has produced or sponsored the material.

17. Representatives/Consumer Promoters

- 17.1 Companies should ensure that representatives/consumer promoters have adequate training to ensure sufficient scientific knowledge of the medicines which they promote to enable the provision of precise and complete information about such medicines.
- 17.2 All materials including slides and handouts shall comply with the requirements of the Code.
- 17.3 Product training must be consistent with the package insert of a medicine.
- 17.4 Representatives/consumer promoters must notify their company regarding any information received in relation to the use of medicines which they promote, particularly any information relating to adverse event reporting.
- 17.5 Consumer promoters are to conduct the promotion of product in a professional manner, and are not permitted to disparage any opposition products.

18. Compliance with Undertakings

When an undertaking has been given in relation to a ruling under the Code, the company concerned must ensure compliance with that undertaking.

PART II - Enforcement

1. MARKETING CODE AUTHORITY

The Code of Practice for the Marketing of Medicines in South Africa is administered by an industry self-regulatory body, the **Marketing Code Authority** [the Code Authority].

The Code Authority is responsible for:

- the provision of advice, guidance and training on the Code as well as for handling complaints and the complaints procedure.
- arranging for conciliation between companies when requested to do so
- scrutinising journal advertising and Internet or electronic advertising on a regular basis.
- Routinely reviewing the Code and guidance notes
- Compiling and publishing reports on complaints received by the Code Authority half yearly and distributed to Department of Health.

1.2 STRUCTURE AND RESPONSIBILITIES OF THE MARKETING CODE AUTHORITY

The Code Authority consists of:

- Board
- The Secretariat, which consists of a Director and administrative personnel as necessary
- The Marketing Adjudication Panel,
- The Marketing Appeal Board

The Board of Management of the Code Authority should consist of two Executive members nominated by each trade association viz. the Pharmaceutical Industry Association of South Africa' [PIASA], the National Association of Pharmaceutical Manufacturers [NAPM], Innovative Medicines South Africa [IMSAs], the Self-Medication Association of South Africa [SMASA], National Association of Pharmaceutical Wholesalers [NAPW] and may include a representative from government.

The term of office of the Board of Management members is 2 years. To ensure continuity, one third of the members shall retire after the first two years and new members shall be elected to replace them. The Board will do a biennial review on the Marketing Code principles, enforcement and governance.

All trade associations endorsing the Code can nominate potential candidates to the Marketing Adjudication Panel and Appeal Board. The Board would appoint the Director of the Code Authority who would report to the Board and the Marketing Adjudication Panel and Appeal Board.

As a condition of appointment, all members of the Marketing Adjudication Panel and Appeal Board must sign a confidentiality agreement regarding their deliberations and must recuse themselves from any meetings or hearings where there could be a conflict of interest.

1.3 Director

The Director manages the administrative staff, the Marketing Adjudication Panel and the Marketing Appeal Board.

The Director has the authority to request copies of any relevant material from a marketer or supplier of medicines, including copies of the certificates authorising any such material and copies of relevant briefing material for representatives.

The Director may consult the Marketing Adjudication Panel or the Marketing Appeal Board upon any matter concerning the Code or its administration.
 The Director has the power to screen out frivolous complaints or those abusing the system.

1.4 FUNDING OF THE CODE AUTHORITY

All companies will pay an annual membership fee directly or via their respective trade associations to the Code Authority. Additional funds will be from complaints i.e. a lodging fee and administrative fee and for training stakeholder on the Code. The Board will agree on a fee schedule for the Chairperson of the Appeal Board. Members of the Board, Panel and Appeal Board will not be reimbursed or paid for their time.

2. COMPLAINT HANDLING

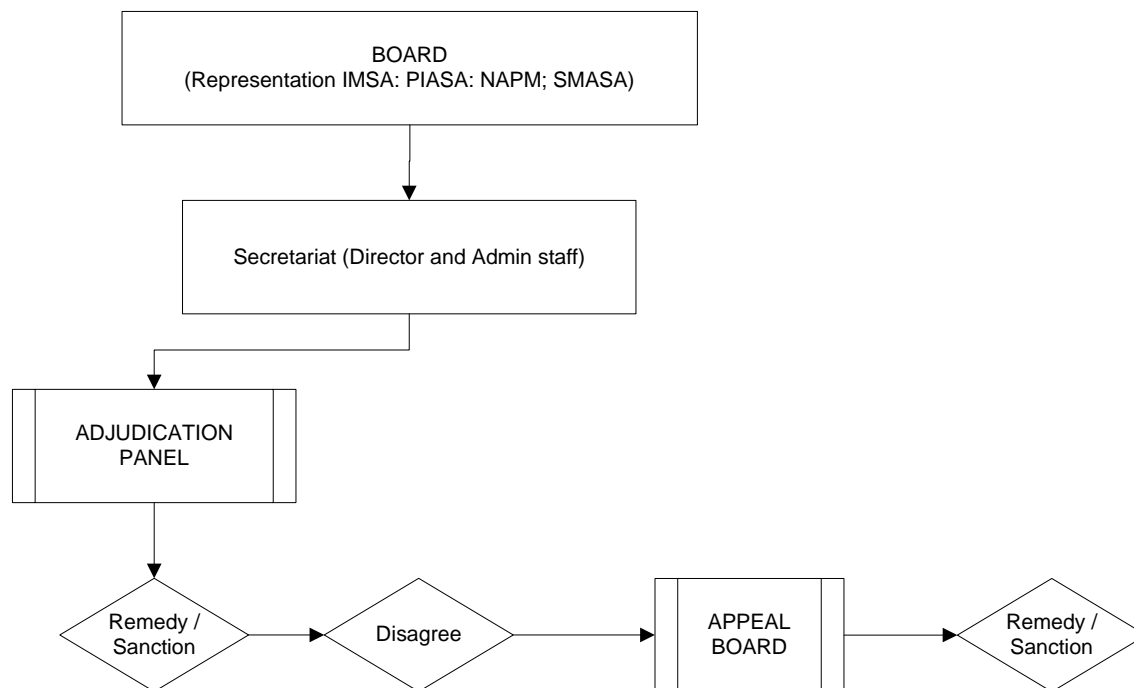
2.1 Procedure for handling complaints

Complaints made under the Code about promotional material or the promotional activities relating to the marketing of medicines are considered initially by the Director.

Where appropriate, the Marketing Adjudication Panel, and if necessary, the Marketing Appeal Board will review the complaint and make a recommendation.

The meetings of both the Marketing Adjudication Panel and Appeal Board will be in closed sessions. The meetings will be fully recorded and minuted by the Director. Deliberations of the Panel and the Appeal Board will not be recorded and only the findings will be minuted.

The basic process is represented in the flow diagram below.



3 COMPLAINTS PROCEDURE

Complainants are encouraged to contact the company, organisation or individual concerned prior to lodging a complaint, as a satisfactory solution may be immediately available.

3.1 Complaints from consumers and other persons outside the Industry

Where a consumer or other person outside the industry makes a complaint, the complainant may simply state the nature of the conduct to which objection is taken and give the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

The company, organisation or individual whose conduct is the subject of the complaint must be given full details of the complaint. The chief executive of the company or organisation or the individual concerned [the respondent] is requested to comment on the matter of the complaint within seven [7] working days.

The Director will provide to the complainant a copy of the respondent's response. The complainant may deliver to the Code Authority within five [5] working days, any reply it wishes to make. The Director will send a copy of the complainant's reply [if any] to the respondent.

3.2 Industry generated complaints

3.2.1 Internal process by Code Authority

Informal process

Companies and/or organisations are encouraged to seek resolution of their differences informally before invoking the formal procedures. No informal communications will be acted upon by the Code Authority.

Formal process

Complaints must be lodged in writing to the Director of the Code Authority within 30 days of knowledge of the promotional material. The submission should include:

- a copy of the advertisement or promotional material in question;
- copies of any studies relied on;
- explain why it is said that this Code has been contravened;
- specify the section or sections of this Code said to have been contravened;
- identify the category of breach.

When a complaint is made, the complainant must state the nature of the conduct to which objection is taken and give the reason(s) for the objection. Where the complaint is based on scientific issues, supporting literature is desirable to ensure a balanced review.

If the complaint is resolved by agreement after the initiation of the formal complaint process and before final determination of the complaint, the complainant (or, in the case of an appeal, the appellant) must inform the Director immediately and the complaint [or appeal] will be treated as withdrawn. However the company, organisation or individual contravening the code shall be responsible for meeting the costs of the complaint up to that point.

The Director can request additional information from either the complainant or respondent e.g. study protocol, ethics and / or MCC approval, detailer material, unpublished data etc.

3.3 MARKETING ADJUDICATION PANEL

The Marketing Adjudication Panel will comprise of 12 individuals appointed by the Board. The members of the Marketing Adjudication Panel shall be appointed for five years. It meets as business requires to review complaints made under the Code.

The Director will invite appropriate members to serve on a Panel. The Panel will include persons with medical, regulatory and marketing. A minimum of 3 members are required for any one hearing. The member's identities will be kept confidential. The Director must be able to substantiate the selection process and keep appropriate records. The Director will not be part of the Panel.

A Chairperson is elected from the Panel. Decisions are made by majority votes.

The Chairperson of the Panel may obtain expert assistance in any field. Expert advisers who are consulted may be invited to attend a meeting of the Panel but will have no voting rights.

The panel will decide on the remedy and sanctions for each case.

There will be no legal representation of either the complainant or respondent. This does not preclude parties from obtaining legal advice.

3.3.1 MARKETING ADJUDICATION PANEL RULINGS

Where the Marketing Adjudication Panel rules that there is a breach of the Code:

- the company, organisation or individual concerned is so advised and is given the reasons for the decision.
- The respondent has ten [10] working days to provide a written undertaking that the promotional activity or use of the material in question (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future.
- This undertaking must be signed by the chief executive of the respondent or by the individual respondent or by the Company Code Compliance Officer.
- The undertaking must be accompanied by details of the actions taken by the respondent to implement the undertaking, including the date on which the promotional material was finally used /or the last date on which the promotional activity took place, and confirmation that the corrective steps, if any, as determined by the Panel have been taken publicly to undo the damage caused by the breach of the Code.
- The respondent must also pay within twenty working days, an administrative charge based on the number of matters ruled in breach of the Code.

Where the Director or Panel rules that there is no breach of the Code:

- the complainant and respondent are so advised.
- Where the complaint is from a pharmaceutical company, or other business organisation, the complainant must pay, within twenty working days, an administrative charge based on the number of matters alleged and ruled not to be in breach of the Code.
- When advised of the outcome, the complainant will be sent a copy of the comments and enclosures submitted by the respondent in relation to the complaint.

The complainant or the respondent may appeal to the Marketing Appeal Board against rulings of the Director or the Panel.

- Appeals must be lodged within ten working days of the notification of the ruling of the Director or Panel and must be accompanied by reasons as to why the Director's or Panel's ruling is not accepted. These reasons will be circulated to the Marketing Appeal Board.
- the respondent has ten working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Marketing Appeal Board.
- The complainant has five working days to comment on the respondent's comments upon the reasons given by the complainant for the appeal and these comments also will be circulated to the Marketing Appeal Board.

3.4 APPEAL BOARD

The Director selects members of the Appeal Board and the Chairperson. The Appeal board will comprise of 3 members including the Chairperson.

The Chairperson shall be a practising advocate or an attorney. Such a person shall be of at least five years standing in South Africa, provided that he or she shall not have been a member of the Panel, whose decision is the subject matter of the appeal.

The other members of the Appeal Board should have medical and / or regulatory skills and experience.

When appeals are considered by the Marketing Appeal Board, both the complainant and the respondent are entitled to appear or to be represented. Decision is made by majority votes.

Where an appeal is brought which is concerned with an issue of fact between a complainant and the respondent that cannot be properly resolved without the oral evidence of the persons directly involved, the Chairman may invite such persons to attend and give evidence.

Where a respondent appeals and the Marketing Appeal Board rules that there was *no breach* of the Code

- the respondent must pay, within twenty working days, an administrative charge based on the number of matters taken to appeal on which no breach is ruled.

Where the Marketing Appeal Board rules that there *is* a breach of the Code

- the respondent is so advised in writing and is given the reasons for the decision. The respondent then has five working days to provide a written undertaking providing the information specified in above paragraph.

The company, organisation or individual promoting or marketing the medicine must also pay within twenty working days, an administrative charge based on the number of matters ruled in breach of the Code.

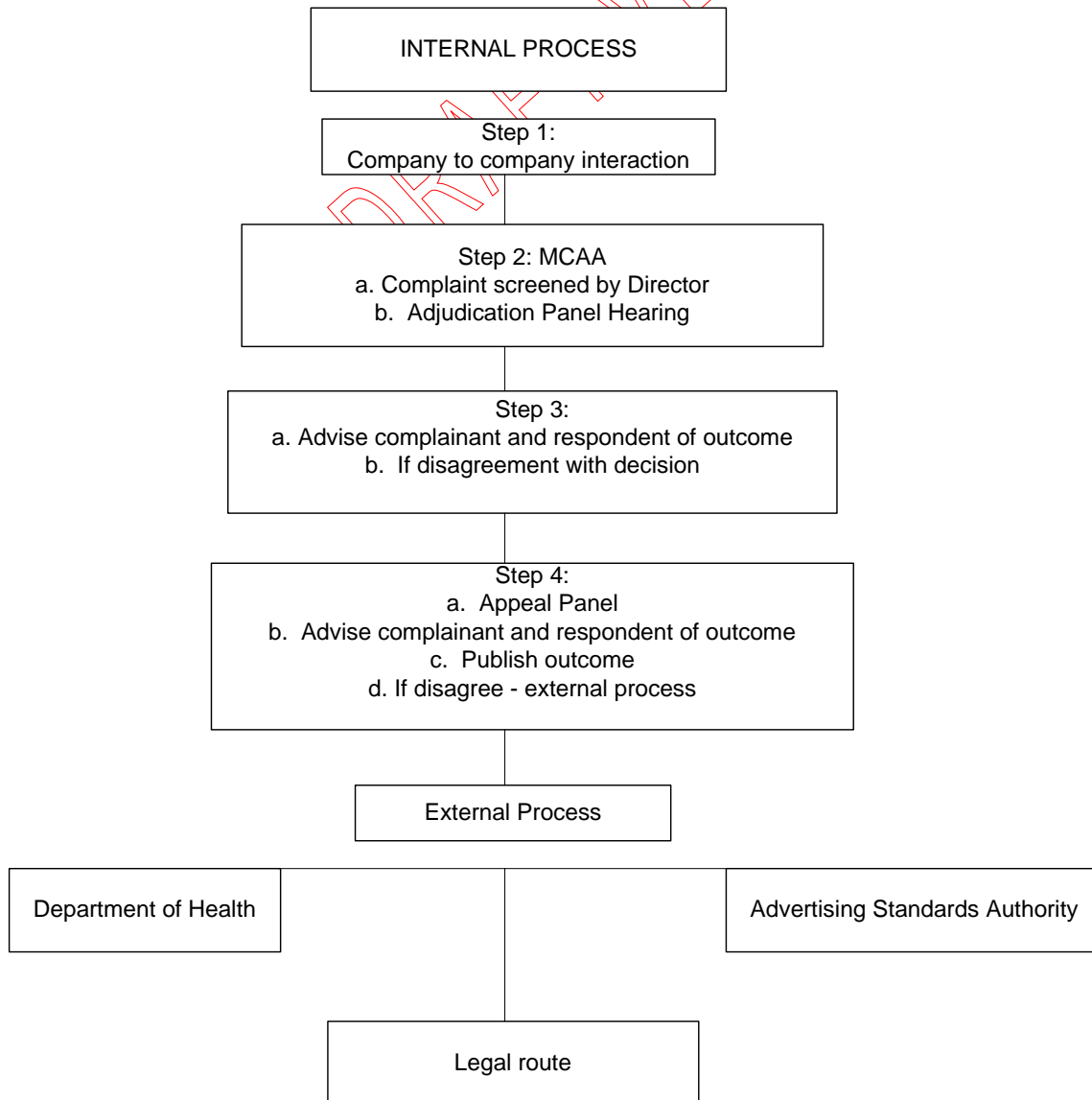
A company, organisation or individual ruled in breach of the Code may also be required by the Marketing Appeal Board to take steps to recover items given in connection with the promotion of a medicine. Details of the action taken must be provided in writing to the Marketing Appeal Board.

Failure or refusal of a company or organisation or individual to comply with the decisions of the Code Authority shall be reported to the Marketing Appeal Board for consideration.

The Marketing Adjudication Panel may also report to the Marketing Appeal Board any company, organisation or individual whose conduct in relation to the Code, or in relation to a particular case before it, warrants consideration by the Marketing Appeal Board for possible further sanctions against the company organisation or individual. Such a report to the Appeal Board may be made notwithstanding the fact that a company organisation or individual has provided an undertaking requested by the Panel.

Where the Panel reports a company, organisation or individual to the Marketing Appeal Board, the company, organisation or individual concerned, is provided with a copy of the report prior to its consideration and is entitled to have a representative or representatives appear before the Appeal Board to state the company's, organisation's or individual's case.

Summary



4. SANCTIONS

4.1 Breaches

Where a breach of the Code has been established, the Marketing Adjudication Panel and / or Appeal Panel, must classify what kind of breach has occurred, in accordance with the classification set out below:

Class 1 Breach: a breach of the Code that has no safety implications and will have no effect on how consumers or healthcare professionals view the product or its competitors.

Class 2 Breach: a breach of the Code with no safety implications but which will impact on the perceptions of the consumer or healthcare professionals regarding the product or competitor product.

Class 3 Breach: a breach of the Code that has safety implications or will have a major impact on how consumers or healthcare professionals view the product or competitor products.

Repeat Breach: when the same or a similar breach is repeated in the promotion of either a particular product, or any product or practice of a company organisation or individual which had been found to be in breach of the Code within the preceding 24 months.

Legal Breach: Contravention of requirements of relevant Acts – to be referred to the DoH for action
When the Panel has made a ruling, this should be communicated to the respondent company, organisation or individual and the relevant trade association where applicable.

4.2 SANCTIONS

After classifying the breach, the Director must consider whether or not any sanction will be imposed. The Director is not obliged to impose a sanction where breaches of the Code have not been established.

In determining whether or not to impose a sanction and, if so, what that sanction should be, the Director will consider all the circumstances of the case, including whether:

- publication has ceased;
- steps have been taken to withdraw the material published;
- corrective statements have been made;
- the breach was deliberate or inadvertent;
- the company, organisation or individual that is the subject of the complaint has previously breached the Code;
- there were or are safety implications;
- the perceptions of healthcare professionals or consumers have been or will be affected.
- how widely material was distributed.

4.2.1 Possible sanctions:

- Undertaking to discontinue advertising/activity
- Retraction and/or corrective statements
- Audit of company procedures
- Fines

4.3 Abuse of the Code

If, in the course of hearing a complaint lodged by an industry member, the Marketing Adjudication Panel considers that the complaint has been submitted as a competitive tool and for vexatious reasons, the Marketing Adjudication Panel may request the complainant to show cause why the Marketing Adjudication Panel should not impose an order for costs for vexatious use of the Code.

4.4 Non-compliance with the Sanction

Failure of the offending company to comply with any of the above sanctions shall entitle the Marketing Adjudication Panel to direct the Secretariat to:

- notify the Department of Health with a full report of the complaint and the finding of the Adjudication Panel,
- publish in national newspapers or appropriate publications details of the breach of the Code, the Code's sanction and consequent requirements for remedial action, at the expense of the company, organisation or individual involved.

5. REPORTS

5.1 REPORTS TO DEPARTMENT OF HEALTH OR ADVERTISING STANDARDS CODE AUTHORITY

Where the Marketing Adjudication Panel or Marketing Appeal Board considers that the conduct of a company, organisation or individual in relation to the Code or a particular case before it warrants such action, it may report the company, organisation or appropriate person / relevant department with the Department of Health or Advertising Standards Code Authority, [ASA], as appropriate for consideration of application of further sanctions against that company, organisation or individual. Such a report may be made notwithstanding the fact that the company or organisation has provided an undertaking requested by either the Marketing Adjudication Panel or the Marketing Appeal Board.

The company, organisation or individual concerned is provided with a copy of the report to be submitted to the Department of Health or ASA and is entitled to have a representative or representatives appear before the Code Authority to state the company's, organisation's or individual's case before the report is made available to the Department of Health for further sanction.

5.2 CASE REPORTS

At the conclusion of any case under the Code, the complainant will be advised of the outcome and a report will be published summarising the details of the case.

The respondent company, organisation or individual and the medicine concerned are named in the report. In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body is named in the report. The information given must not, however, be such as to identify any individual person.

A copy of the report on a case is made available to both the complainant and the respondent prior to publication. Any amendments to the report suggested by these parties are considered by the Director, consulting with the other party where appropriate. If either party does not accept the Director's decision as to whether or not a report should be amended, the matter is referred to the Chairman of the Marketing Adjudication Panel/Marketing Appeal Board for a decision.

Copies of all case reports will be submitted to the Marketing Adjudication Panel and the Marketing Appeal Board prior to publication. Copies of the published reports will appear in a newsletter of the Code Authority on a website. Copies of the published reports are also available to anyone on request.

6. GENERAL PROVISIONS

6.1 Compliance

Compliance with the Code is mandatory for all for all manufacturers, suppliers, distributors and marketers of medicines in South Africa.

6.2 Time Periods for Responding to Matters under the Code

The number of working days within which respondents or complainants must respond to enquiries etc, from the Code Authority as referred to in the above procedures, are counted from the date of receipt of the notification in question. An extension in time to respond to such notifications may be granted at the discretion of the Director of the Code Authority.

6.3 Withdrawal of Complaints

A complaint may be withdrawn by a complainant with the consent of the respondent up until such time as the respondent's comments on the complaint have been received by the Code Authority but not thereafter.

6.4 Notices of Appeal –withdrawal by a complainant

Notice of appeal may be withdrawn by a complainant with the consent of the respondent up until such time as the respondent's comments on the reasons for the appeal have been received by the Code Authority, but not thereafter.

6.5 Notices of Appeal –withdrawal by a respondent

Notice of appeal may be withdrawn by a respondent at any time but if notice is given after the papers relating to its appeal have been circulated to the Marketing Appeal Board, then a higher administrative charge will be payable.

6.6 Code Levy and Administrative Charges

An annual payment for administration of the Code and the Code Authority must be paid by all marketers of medicines [including but not limited to the holders of the Certificate of Registration for all medicines which have been registered by the MCC/MRA* and are marketed]. If a medicine is registered but not marketed, the company may be requested to provide evidence of that fact. The levy together with the appropriate administrative charges is determined by the Code Authority, subject to approval by the trade associations.

NOTE: All companies, organisations, or individuals marketing medicines are liable for such charges whether they are members of the above trade associations or not.

6.7 Administrative charges for processing complaints

Administrative charges for processing complaints are payable only by marketers and suppliers of medicines who are bound by this Code.

There are two levels of administrative charge.

The lower level is payable by a company, organisation, or individual which accepts either

- the ruling of the Marketing Adjudication Panel that it was in breach of the Code or
- the rejection by the Panel of its allegation against another company, organisation, or individual.

The lower level is also payable by a complainant company, organisation, or individual if a ruling of the Panel that there was a breach of the Code, is subsequently overturned by the Marketing Appeal Board. The higher level is paid by a company organisation, or individual as complainant or respondent that unsuccessfully appeals a decision of the Committee.

6.8 Co-promotion

Where two or more companies, organisations, or individuals are ruled in breach of the Code in relation to a matter involving co-promotion, each company, organisation or individual shall be separately liable to pay an administrative charge.

6.9 Number of administrative charges

The number of administrative charges that apply in a case is determined by the Director of the Code Authority. If a company, organisation, or individual does not agree with the Director's decision, the matter is referred to the Chairman of the Marketing Adjudication Panel or Marketing Appeal Board for a decision.

6.10 No charges by members of the public or non-commercial individuals or organisations

Members of the public, individual health professionals and consumer organizations will not be required to pay administrative charges.

6.11 Possible Breaches identified by the Marketing Adjudication Panel or Marketing Appeal Board

Where the Marketing Adjudication Panel or Marketing Appeal Board identifies a possible breach of the Code which has not been addressed by the complainant in a case, the respondent company is invited to comment. The company has ten working days to respond in writing.

If the company accepts there is a breach of the Code, the company is requested to provide an undertaking to fulfil the requirements specified in Paragraph 10.1 above. No administrative charge shall be payable in these circumstances and there shall be no case reports on the matter in question.

If the company does not accept that there is a breach of the Code, the procedures under Paragraph 8 above and onwards shall be followed. The Code Authority shall act as the complainant in this case.

6.12 Scrutiny of Advertisements

A sample of advertisements issued by pharmaceutical companies is scrutinised by the Code Authority in relation to the requirements of the Code on a continuing basis.

Where a *prima facie* breach of the Code is identified under this procedure, the company concerned is requested to comment in writing within ten working days of receipt of the notification.

If the company accepts there is a breach of the Code, the company is requested to provide an undertaking providing the information specified in Paragraph 10.1 above. No administrative charge is payable in these circumstances.

If the company does not accept there is a breach of the Code, the procedures under Paragraph 8 above and onwards are followed. The Code Authority shall act as the complainant in this case.

6.13 Provision of Advice & Conciliation

The Code Authority is available to provide informal guidance and advice in relation to the requirements of the Code and, where appropriate, may seek the views of the Marketing Adjudication Panel or Marketing Appeal Board.

Companies wishing to seek the assistance of a conciliator with the view to reaching agreement on inter-company differences about promotion may contact the Director of the Code Authority for advice and assistance.

6.14 Amendments to the Code

This Code and Constitution and Procedure may be amended by the Marketing Adjudication Code Authority after consultation with the pharmaceutical industry and other stakeholders.

6.15 Code Authority to conduct audits

The Constitution and Procedure for the Code Authority authorise the Code Authority to carry out an audit of a company's procedures in relation to the Code. The Code Authority will publish guidelines on company procedures that are regarded as representative of good practice in this regard. These are minimum requirements and will need to be adapted to fit in with the arrangements at any particular company.

6.16 Annual Report

An annual report of the Code Authority is published each year with the approval of the Marketing Adjudication Panel and Marketing Appeal Board. This report includes details of the work of the Code Authority, the Marketing Adjudication Panel and the Marketing Appeal Board during that year.

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TRADE ASSOCIATIONS ENDORSING THE SOUTH AFRICAN MARKETING CODE

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Physical Address:

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Vorna Valley
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Telephone Number: 011 805-5100
Fax Number: 011 805 5105 / 9
E-mail Address: info@piasa.co.za
Website: www.piasa.co.za

Postal Address:

P O Box 12123
Vorna Valley
1686

List of PIASA Members:

Abbott Laboratories SA (Pty) Ltd
Adcock Ingram Healthcare (Pty) Ltd
Alcon Laboratories (Pty) Ltd
AstraZeneca Pharmaceuticals (Pty) Ltd
Bayer –Schering (Pty) Ltd Healthcare Division
Boehringer Ingelheim (Pty) Ltd
Bristol-Myers Squibb (Pty) Ltd
Galderma Laboratories (Pty) Ltd
GE Healthcare (Pty) Ltd
Genop Healthcare (Pty) Ltd
GlaxoSmithKline SA (Pty) Ltd
Janssen-Cilag (Pty) Ltd
Key Oncologics
Merck (Pty) Ltd
iNova Pharmaceuticals (Pty) Ltd
Novo-Nordisk (Pty) Ltd
Nycomed Madaus (Pty) Ltd
Schering-Plough (Pty) Ltd
Sekpharma (Pty) Ltd
Servier Laboratories (Pty) Ltd
Solvay Pharma (Pty) Ltd
Stiefel Laboratories SA (Pty) Ltd
Tyco Healthcare (Pty) Ltd
UCB Pharma
Wyeth South Africa (Pty) Ltd

IMSA CONTACT DETAILS:

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Fax Number: 011 880 4644
E-mail Address: info@innovativemedicines.co.za
Website: www.imsa.co.za

List of IMSA members

Novartis South Africa Pty Ltd
Eli Lilly SA Pty Ltd
Sanofi-Aventis
MSD (Merck Sharpe & Dohme)
Pfizer
Roche Products Pty Ltd

SMASA CONTACT DETAILS

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Murrayfield
0184

List of SMASA members

Adcock Ingram
Nycomed Madaus
Bausch & Lomb
Bayer Consumer Care
Boehringer-Ingelheim
Cipla Medpro
GlaxoSmithKline
Johnson & Johnson
Merck (Pty) Ltd
Norgine
Novartis Consumer Health
Pharma Dynamics
Pharmafrica
Proctor & Gamble
Reckitt Benckiser
Smith & Nephew
Thebe Medicare
Winthrop Pharmaceuticals (Sanofi-Aventis)
Wyeth Consumer Healthcare

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Arcadia,
0007

Pretoria, Tel: (012) 3237529

Fax: (012) 3237529

E-mail: napm@mweb.co.za

Website: www.napm.co.za

List of members

Aspen Pharmacare
Austell Laboratories
Be – Tabs
Biovac S.A
Bodene
Columbia
Dr Reddy's
Enaleni
Ferring
Medreich S.A
Merck Generics
NBI
Omnimed
Pharma Dynamics
Pharmafrica
Ranbaxy
Sandoz
Sekpharma
Thebe Medicare

Wholesalers and Distributors

NAPW
ICH
PHD

Community Pharmacy

PSSA
ACP
USAP
Clicks
Dischem

Other bodies or associations

SAMA; HASA
SAMED; BHF

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APPENDIX I: LEGISLATION

- Medicines Act No. 101 of 1965 as amended by Act 90 of 1997 and Act 59 of 2002
- The Code of Practice for the Marketing of Medicines is enforceable –reference Section 18C of Act 90 of 1997 as amended by Act 59 of 2002.
- Regulations under Medicines and Related Substances Act 101 of 1965 as amended
- National Health Act and Regulations
- Medical Schemes Act & Regulations

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[a1]To be discussed with HPCSA for consideration